

# Pharmaceutical Nomenclature Issues and challenges



Moheb M. Nasr, Ph.D.  
Acting Director  
Office of New Drug Chemistry (ONDC)  
OPS, CDER, FDA

Advisory Committee for  
Pharmaceutical Sciences (ACPS)  
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# Pharmaceutical Nomenclature Issues and challenges



FDA Perspective

Dan Boring, R.Ph., Ph.D.

Topical Dosage Form  
Classification - an  
Update

Lucinda Buhse, Ph.D.

Committee Discussions

# Issues and challenges



- Impact on regulatory decisions, marketing, drug development, and the public
- Nomenclature development (scientific and regulatory challenges)
  - How to do it right the first time?
  - Is a new dosage form needed or is it just a minor modification in an existing dosage form that can be handled by labeling?
  - How to establish definitions and criteria for new dosage forms?
  - Do we need to have that many dosage forms?

# Issues and challenges



- Coordination with different organizations and stakeholders
- Definitions (descriptive and quantifiable attributes)
- Refinement and/or replacement of older dosage forms
- Pharmaceutical equivalence issues

# FDA Perspective on Dosage Form Nomenclature



Dr. Dan Boring, R.Ph., Ph.D.  
Review Chemist; Labeling Expert  
ONDC, OPS

# Nomenclature of Pharmaceutical Dosage Forms



- Issues and challenges
  - Scientific
  - Regulatory
  - Marketing
  - Legal
  - Healthcare provider
  - Patient

# What is an Established Name?



- The FD&C Act states “drug” only
- Drug substance and/or drug product?
- At CDER, an established name for both drug substance and drug product
- In general, an established name for a drug product is:
  - [(drug substance) (release characteristic)  
(route of administration) (dosage form)]
- Today’s focus is on dosage form

# Definition of a Pharmaceutical Drug Product



- Drug Product is defined as a finished dosage form such as tablet, capsule or solution
- What is a dosage form?
- A dosage form could be defined as the physical form of a drug product at the point that it is introduced into the body, or, where final preparation is required before introduction into the body, the physical form of the drug product in the package that bears instructions for final preparation (private communication)
- Dosage forms are non-proprietary

# Stakeholders



- Innovators
  - Research, development, marketing, legal
- FDA
  - OND, ONDC, ODS, COS, NSC
- USP
  - Expert Comm on Nomenclature and Labeling
- Healthcare providers and patients
  - Not direct participants

# FDA Nomenclature Issues



- New drugs
  - No USP monograph exists
  - Is a new name necessary?
  - Is it nomenclature or labeling?
- Generic drugs
  - Compliance with USP monograph?
  - Is a compendial name being developed?
  - Will name allow proper product selection for substitution?
  - Name definition should not allow generic manufacturers to substitute a new dosage form for a RLD
- OTC drugs
  - Product selection by patient

# Nomenclature Assessment Factors



- Name must clearly identify the product
- Name promotes accurate recognition without risk of medication errors
- Name meets database, indexing and listing needs
- Name consistent with precedents (i.e., systems)
- Name should not provide an advantage through exclusive proprietary technology

# Challenges



- Will a new name serve long-term needs?
- Is an older term still accurate?
- Is a developing new term appropriate?
- Can objective standards be developed to define a new dosage form?
- How should name development be coordinated (innovator, FDA, USP)?
- Global harmonization?
- Implementation?

# Topical Dosage Form Classification – an Update

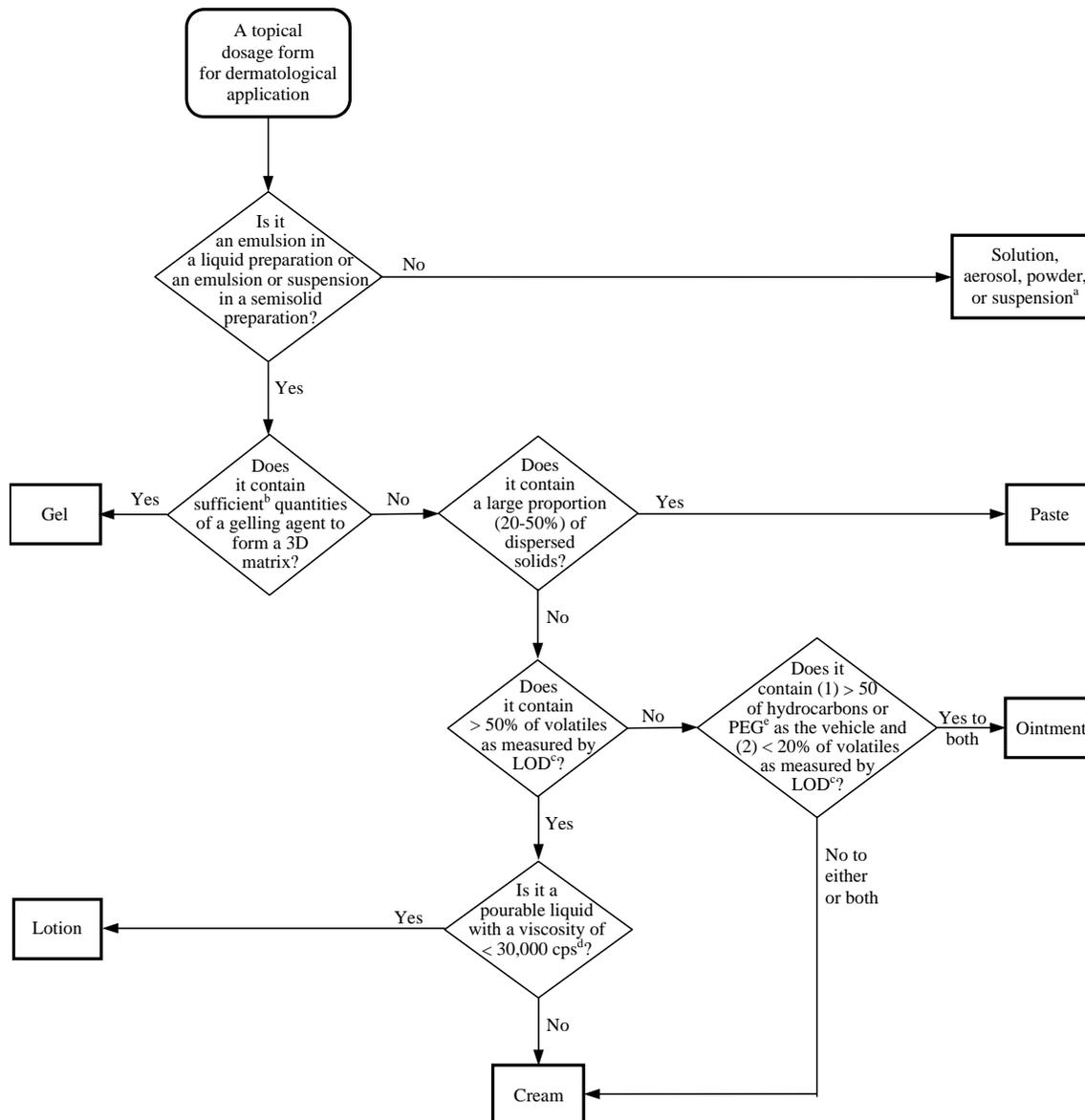


Lucinda Buhse, Ph.D.

Acting Director

Division of Pharmaceutical Analysis  
Office of Testing and Research, OPS

## Decision Tree on Topical Dosage Form Nomenclature (ACPS, March 2003)



# Advisory Committee Input



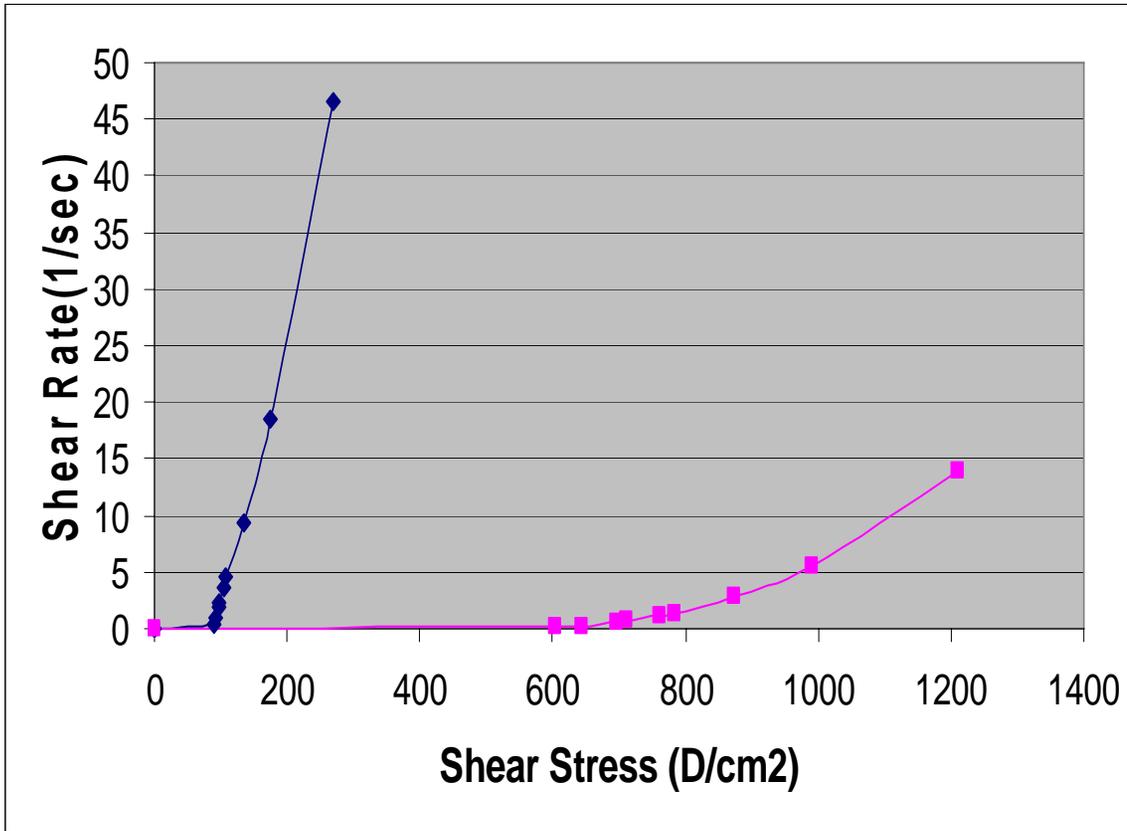
- No need to include appearance and feel (e.g., greasy, non-greasy)
- Definitions should be based on the vehicle
- Ointments and suspensions could be classified as lotions (an overused term)
- Do not make cream a default definition and do not separate creams using hydrophilic-vs-hydrophobic
- Use detailed rheological evaluation (e.g., yield values) to distinguish gels and/or lotions from creams
- Reconsider criteria used to classify gels

# CDER Activities



- Evaluation of ACPS input
- Consultations with Dr. Arthur Kibbe
- Analysis of liquid/semi-solid borderline products based on more extensive rheological evaluation
- Examination of optical properties and compositions of gels

# Rheological Evaluation



Sample	Yield Value (D/cm <sup>2</sup> )	
1	50	↑ Conforms to container
29	90	
62	125	
61	160	
36	195	
50	200	
51	525	↓ Does not conform to container
4	600	
32	660	

# Decision Tree on Topical Dosage Form Nomenclature

10/14/03

